

internal shapes. Suitable shapes can include, but are not limited to, a substantially rectangular structure, a substantially rectangular shape with rounded corners, a cylinder, a cylindrical structure with a substantially oval cross-section, and other like shapes.

[0030] According to an exemplary embodiment, the exterior surface of the first wall includes a heating circuit comprising a resistive electrical path fabricated on the surface with a first and second connecting pad for contacting an external circuit for providing current flow through the path. Moreover, the exterior surface of the first wall can be equipped with a temperature sensor comprising, for example, a thermistor or thermocouple fabricated on the surface and further equipped with first and second connecting pads for contacting an external circuit for electrical connection with the thermistor or thermocouple.

[0031] As described further herein, the sample entry orifice of the inventive device is capable of mating with a sample introduction element comprising a wand with a first end with an absorbent pad capable of collecting and retaining a nucleic acid sample and a second end forming a handle. The first end is capable of passing through the sample entry orifice into the chamber, where the wand has an engaging means between the first and second end for engaging and sealing the wand in the sample entry orifice.

[0032] According to a preferred exemplary embodiment of the present invention, the amplification chamber contains a polymerase and dNTPs, optionally, one or more primers and/or buffers. The amplification chamber can further contain a sugar glass coating on at least a portion of the interior surface of the first wall. The sugar glass coating can comprise a reagent selected from the group consisting of a buffer, a dye, one or more primers and a polymerase. The amplification chamber is preferably capable of withstanding a temperature increase ramp rate in the range of about 10 to about 50° C. per second, more preferably, about 4 to about 50° C. per second. The amplification chamber can further comprise an optical window.

[0033] It should be noted that the inventive device is capable of engaging and being operated by an instrument, preferably a hand-held instrument. Such an instrument can be equipped with a fan that is capable of cooling the amplification chamber. Alternatively, the instrument can include a heat-sink capable of reversibly contacting and cooling the amplification chamber. What is more, the exterior surface of the first wall can include a Peltier circuit with a first and second connecting pad for contacting an external circuit.

[0034] The inventive device according to exemplary embodiments is preferably equipped with a reversible seal on the ingress. The reversible seal can comprise a flexible diaphragm. The flexible diaphragm can be capable of actuation into a closed position by an applied force, and an open position by the absence of the applied force. For instance, the applied force can be provided by another device, for example, an instrument with which the inventive device is engaged, which instrument might be equipped with a pin that can mate with the flexible diaphragm. The inventive device can also be equipped with a reversible seal on the egress. The reversible seal can comprise a flexible diaphragm. Such a flexible diaphragm can be capable of actuation into a closed position by an applied force, and an open position by the absence of the applied force. For instance, the applied force can be provided by another

device, for example, an instrument with which the inventive device is engaged, which instrument might be equipped with a pin that can mate with the flexible diaphragm.

[0035] According to an exemplary embodiment, the inventive device can include a conduit that is capable of permitting egress of the amplicon, and which has a mating feature for engaging a separate device for detection of the amplicon. In one exemplary embodiment, the ingress and the egress are at opposite corners of the amplification chamber.

[0036] A sample entry orifice is also provided with the inventive device that is capable of mating with a sample introduction element. The sample introduction element can comprise, for example, a wand that, in turn, can comprise a first end with an absorbent pad capable of collecting and retaining a nucleic acid sample and a second end forming a handle. The first end can be capable of passing through the aforementioned sample entry orifice into the amplification chamber. Furthermore, the wand can include an engaging means between the first and second end for engaging and sealing the wand in the sample entry orifice. In a preferred exemplary embodiment, the engaging and sealing means can comprise a male screw feature on the wand and a female screw feature on the sample entry orifice. In another exemplary embodiment, the engaging and sealing means can comprise a male collar locking feature on the wand and a female collar locking feature on the sample entry orifice.

[0037] In yet another exemplary embodiment of the present invention, the conduit connected to the ingress can further comprise a chip insert equipped with a fluid detection sensor. In particular, a portion of the chip can be preferably coated with a nucleic acid amplification reagent. A wide variety of nucleic acid amplification reagents can be coated onto a portion of the chip, including, but not limited to, a buffer, a dye, one or more primers, dNTPs, a polymerase, and the like. Nucleic acid amplification reagents can also be coated elsewhere in the inventive device, such as the conduit connected to the ingress.

[0038] Therefore, a combination is also contemplated and provided by the present invention, which combination includes a single-use nucleic acid amplification device for producing an amplicon and an instrument for engaging and operating this device. Preferably, such device comprises a housing, an amplification chamber comprising an ingress with a reversible seal, an egress with a reversible seal, a sealable sample entry orifice, and a first wall forming a portion of the amplification chamber. The first wall comprises a thermally conductive material having an interior surface and an exterior surface, wherein the exterior surface has a heating circuit and a temperature sensor. The sample entry orifice permits a sample of nucleic acid to enter the amplification chamber. The ingress is connected to a conduit with a pneumatic pump means and a fluid pouch, while the egress is connected to a conduit permitting egress of the amplicon from the chamber.

[0039] The instrument, which can be portable and battery powered, is equipped with a recess for receiving and engaging the device. Moreover, the instrument can be further equipped with electrical connector means for contacting the heating circuit and the temperature sensor. The instrument can also be provided with mechanical connector means for reversibly engaging the ingress seal, the egress seal, the pneumatic pump means and the fluid pouch. In a particular exemplary embodiment of the present invention, the instru-